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1 Think you're seeing double? Nope, it's just Terri's twin, Sherry!

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1 Her degree in biology and a long history in sales, marketing and project management mean Sherry Keogh is a valuable new resource for Solutions2Projects.

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Wonder Twin Power: Activate!

Look for Sherry to provide everything from marketing campaigns and training to validation and documentation for clients.

Solutions2Projects is now available remotely. Two projects have already been successfully executed remotely — something

to keep in mind if you aren't in the Bay Area (see page 2 article, "Need Not Be Present to Win" for recent project details).

Call us to see how these new developments have added to our ability to make your next project a success!

Strong Project Leadership and Creativity Drive Success Despite Major Obstacles

A recent project at a device client site justified the need for strong and creative project leadership.

Solutions2Projects was contracted to implement a complaint handling and CAPA system, including hardware qualification, in just 3 months — an aggressive timeframe that demanded a trouble-free implementation.

Unfortunately, that was not to be the case. A week after beginning the project, the client company was acquired, resulting in uncertainty and distraction among the project team and steering committee members.

Fortunately, Solutions2Projects had begun an internal marketing campaign to get everyone on board. This proved to be helpful in keeping the project team focused, motivated and energized (see *Solutions*, Volume 2, Issue 1, "Increase Adoption Through Behavior Modification," for details on internal marketing campaigns).

The next obstacle involved vendor resource issues. The first consultant assigned by the vendor became unavailable shortly after beginning the project. The second was only available for a couple of days. The third didn't have the required skill set to provide adequate support.

Solutions2Projects stepped in and took control, by identifying the gaps, learning and becoming an expert on the software, and finally, getting the software implemented, configured and validated. This kept the project on schedule.

However, halfway through the project, one of the stakeholders determined that the software did

not satisfy a key requirement. Solutions2Projects identified a way to satisfy the requirement with new functionality in another system, without significantly impacting the schedule. (See *Solutions*, Volume 2, Issue 1, "What Does it Take to Meet an Aggressive Timeline?", for more information on meeting aggressive timelines).

The obstacles could have delayed or derailed the project. But with creativity and strong leadership provided by Solutions2Projects, the project was successfully completed with only a two week delay.

A Good Consultant Works Herself Out of a "Job"

Consultants are hired to provide a service that is not available at the time — the skill set, bandwidth, or headcount is missing from the organization. The intention is not to hire permanently; the consultant is there to provide interim solutions.

However, in some cases, the organization begins to rely so heavily on the consultant that it becomes difficult to foresee a future without him or her.

At Solutions2Projects, we try to work ourselves out of a "job" by making this transition effortless.

At a recent client site where Terri was acting as a

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Targeted Tips

- Strong project leadership can make a difference when obstacles arise during aggressively timed-projects.
- A good consultant works herself out of a "job" by laying a solid foundation for her successor.
- Map your business and operation requirements to SOX controls to ensure they makes business sense.
- Regulatory and business experience are key to achieving a successful SOX audit.

Need Not Be Present To Win

It's not always necessary to have a full-time consultant on-site to get a project done. In fact, sometimes it's easier to take advantage of available technology.

Solutions2Projects was recently hired by a biotech company in Southern California to help formalize IT processes and prepare a network qualification plan. To avoid wasting time and save on travel costs, Terri and the client agreed to carry out the project remotely.

Via telephone and email, Terri discussed goals, identified gaps, and provided timelines, drafts, edits, and guidance so the client could hit the targeted deadlines.

The project was completed quickly and efficiently. The client didn't need to hire a full-time employee, find a desk for a consultant, or pay for costly travel time. He just had to pick up the phone or respond to email, taking advantage of technology already available.

Targeted Solutions For IT Success


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At Solutions2Projects, we believe that the best way to implement systems in a regulated environment is to establish reasonable processes and adhere to them. We understand that every company is different and at varying stages of the drug development lifecycle, requiring different levels of formalized processes. We tailor our services to meet individual client needs.

Solutions2Projects offers targeted solutions in:

- Project Management
- Corporate Compliance
- Computer Validation
- Other services that augment companies' current capabilities

For additional information, please contact Terri Mead at terri.mead@solutions2projects.com

Regulatory and Finance Experience Instrumental in Successful SOX Audit

Achieving Sarbannes-Oxley (SOX) compliance can seem a formidable task for an IT department, especially when it is just beginning the process. Internal auditors are hired. External auditors are ready to discover mistakes. What can be done?

Finding someone with experience in finance and regulatory compliance is critical for an IT department to navigate its way to a successful audit.

A recent experience at a client site proved just how valuable this type of experience is in achieving SOX compliance

The client decided to use a previously implemented product lifecycle management (PLM) system as a repository for SOX objects and evidence. They asked Solutions2Projects to help implement this new function.

Terri was able to map out the requirements to their business, regulatory requirements, and operations. She brought with her a strong under-

standing of FDA compliance and business and financial processes, which proved to be critical for minimizing duplicated processes. She was able to ensure that multiple requirements were satisfied with the least amount of effort. Plus, everyone got on the same page and knew what they had to do.

Terri also brought a high level business perspective that came in handy when considering which requirements and controls made business sense and which did not, thus reducing the amount of work that had to be done.

In the end, Terri proved instrumental in getting the client through their first audit, successfully and with relative ease.

Having regulatory and finance experience provided value to the organization by minimizing both duplication of effort and required work for the IT group, as well as by providing guidance toward a successful SOX external audit.

A Good Consultant Works Herself Out of a "Job"

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business analyst, she helped hire a full time replacement, provided interim support for the newly hired business analyst, but most importantly, she established a solid foundation from which the new business analyst could work.

This foundation started as soon as Terri began working with the client. She provided good documentation and followed sound business

practices. She was also consistent, so the new analyst could easily follow what had been done.

Terri's full time successor smoothly transitioned into her new role. According to the client, the new business analyst would have been lost without the foundation Terri established.

Independence from full-time consultants can be achieved when the groundwork is in place for an effortless transition.